



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Corey *et al.*  
Filing Date: April 30, 2001  
Application Serial No.: 09/844,816  
Title: TRYPSIN SUBSTRATE AND DIAGNOSTIC DEVICE,  
AND METHOD OF USING SAME

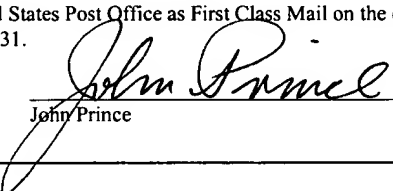
Group: 1627  
Examiner: Guo, Lynda T.

Atty. Docket No.: 038484-0067 (BYRK-19) (previously MSE #2609)

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

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November 25, 2002  
Date

  
John Prince

**TRANSMITTAL LETTER**

Commissioner for Patents  
Washington, D.C. 20231

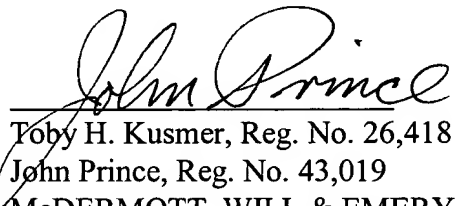
Transmitted herewith for filing are the following documents:

- ☒ an Information Disclosure Statement (2 pp.);
- ☒ a Form PTO-1449 (1 pg., in duplicate);
- ☒ copies of references A1-A12, B1-B3 and C1-C13; and
- ☒ a return postcard

The Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Acct. No. 50-1133.

Respectfully submitted,

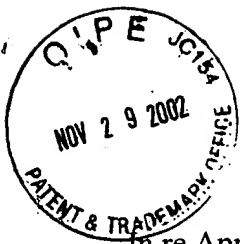
Date: November 25, 2002

  
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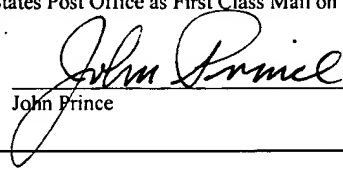
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231


Applicants and their attorney are aware of the publications and information listed on the attached Form PTO-1449, and in accordance with 37 CFR 1.97 hereby submit these publications for the Examiner's consideration.

This Statement is being filed before the receipt of an official action on the merits from the U.S. Patent & Trademark Office. Accordingly, no fee is believed to be necessary. 37 C.F.R. 1.97. However, the Commissioner is hereby authorized to charge any necessary fees to Deposit Account No. 50-1133.

Regarding related patent applications, a divisional application was filed on November 4, 2002.

Applicants note that the submitted U.S. Pat. No. 3,897,214 is related to and contains the same disclosure as French patent 2,170,397, issued Sept. 14, 1973 to Boehringer Mannheim GmbH. The French patent is cited in the specification.

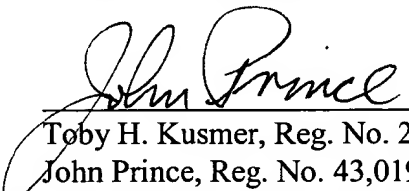
This Statement should not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information

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Application Serial No.: 09/844,816

exists. Nor should the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands that the Examiner will make an independent evaluation of the cited publications.

Respectfully submitted,

Date: November 25, 2002

  
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Modified Form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

<b>Application Number</b>	09/844,816
<b>Filing Date</b>	April 30, 2001
<b>Inventor</b>	Corey <i>et al.</i>
<b>Group Art Unit</b>	1627
<b>Examiner Name</b>	Guo, Lynda T.
<b>Attorney Docket Number</b>	038484-0067 (BYRK-19)

**U.S. PATENT DOCUMENTS**

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentees or Applicants	Class	Sub Class	Filing Date If Appropriate
	A1	3,552,928	01/05/71	Fetter	23	253	07/19/67
	A2	3,846,247	11/05/74	Kronish <i>et al.</i>	195	127	09/27/72
	A3	3,897,214	07/29/75	Lange <i>et al.</i>	23	253	11/13/72
	A4	4,046,513	09/06/77	Johnston	23	253	06/30/76
	A5	4,046,514	09/06/77	Johston <i>et al.</i>	23	253	11/24/76
	A6	4,551,428	11/05/85	Berger <i>et al.</i>	435	19	05/05/81
	A7	4,645,842	02/24/87	Corey	548	541	04/06/84
	A8	4,657,855	04/14/87	Corey <i>et al.</i>	435	19	04/06/84
	A9	4,717,658	01/05/88	Michaels	435	19	12/03/85
	A10	4,704,460	11/03/87	Corey	549	65	04/25/86
	A11	4,774,340	09/27/88	Corey <i>et al.</i>	548	541	04/25/86
	A12	5,750,405	05/12/98	Albarella <i>et al.</i>	436	88	03/01/96

**FOREIGN PATENT DOCUMENTS**

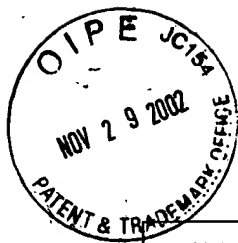
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentees or Applicants	Date of Publication	Translation Yes No
	B1	GB 1,349,623	Boehringer Mannheim GmbH	04/10/74	
	B2	GB 1,369,139	Boehringer Mannheim GmbH	10/02/74	
	B3	JP 11-75896	KDK Corp	03/23/99	x

Examiner  
SignatureDate  
Considered

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<b>Modified Form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)	<b>Application Number</b>	09/844,816
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	<b>Group Art Unit</b>	1627
	<b>Examiner Name</b>	Guo, Lynda T.
	<b>Attorney Docket Number</b>	038484-0067 (BYRK-19)

OTHER NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Publication, Volume, Pages, Date, Etc.
	C1	Aogaichi T & Plaut GWE, "Assay of the esterase activity of thrombin, plasmin and trypsin with a chromogenic substrate p-nitrobenzyl p-toluenesulfonyl-L-arginine", <i>Thrombos. Haemostas. (Stutg.)</i> 37: 253-261 (1977)
	C2	Baustert JH <i>et al.</i> , "Fluorometric continuous kinetic assay of $\alpha$ -chymotrypsin using new protease substrates possessing long-wave excitation and emission maxima", <i>Analytical Biochemistry</i> 171: 393-397 (1988)
	C3	<i>Chem Sources-U.S.A.</i> (Chemical Sources International, Inc., 1999) [Title Page]
	C4	Desnuelle P, "Trypsin", <i>The Enzymes, Second Edition</i> , Chapter 6, pp. -119-132 (Academic Press, New York and London, 1960)
	C5	Goldberg JA & Rutenburg AM., "The colorimetric determination of leucine aminopeptidase in urine and serum of normal subjects and patients with cancer and other diseases." <i>Cancer 11</i> : 283 (1958)
	C6	Gray CJ <i>et al.</i> , "4-methylumbelliferyl esters as fluorogenic substrates for proteases." <i>Enzyme Microb. Technol.</i> 5: 137 (1983)
	C7	Higashi S <i>et al.</i> , "Tissue Factor Potentiates the Factor VIIa-catalyzed Hydrolysis of an Ester Substrate", <i>J. Biol. Chem.</i> 267(25): 17990-17996 (September 5, 1992)
	C8	Inouye K <i>et al.</i> , "Synthesis of TACK, a new chloromethyl ketone derivative of arginine.", <i>Bull. Chem Soc. Japan</i> 47(1): 202 (1974)
	C9	Jensen KA & Crossland I, "Studies of thioacids and their derivatives. VII. On 2-phenyl-4(5H)-thiazolone." <i>Acta Chem. Scand.</i> 17: 144 (1963)
	C10	Kuwajima S <i>et al.</i> , "Automated measurement of trypsin inhibitor in urine with a centrifugal analyzer: comparison with other acute phase reactants." <i>Clin. Biochem.</i> 23: 167 (1990)
	C11	Leytus SP <i>et al.</i> , "Rhodamine-based compounds as fluorogenic substrates for serine proteinases", <i>Biochem. J.</i> 209: 299-307 (1983)
	C12	Piette AM <i>et al.</i> , "Urinary trypsin inhibitory activity for the diagnosis of bacterial infection: a prospective study in 690 patients." <i>European J. Med.</i> 1: 273 (1992) [Abstract]
	C13	<i>Technical Data on Methods of Measuring Urinary Trypsin Inhibitor (UTI)</i> (Sakamoto, Kyoto Daiichi Kagaku Co., Ltd., February 25, 1997)

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

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